REMARKS

The Office Action mailed September 13, 2007, has been carefully reviewed. By this Amendment, Applicants have added claims 25-34. Claims 1-10 and 24-34 are pending in the application. Claims 1 and 25 are independent.

The Examiner provisionally rejected claims 1-10 and 24 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-7, 9, 10 and 23 of copending application Serial No. 10/578,972. Applicants request that further response in connection with this issue be deferred pending the identification of allowable subject matter in one or both of the subject applications.

The Examiner rejected claims 1-10 and 24 under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2005/0033237 to Fentress et al. ("Fentress") taken together with either U.S. Patent No. 4,404,159 to McFarlane or U.S. Patent No. 3,694,280 to Hoef. Also under 35 U.S.C. 103(a), the Examiner rejected claims 1-10 and 24 as being unpatentable over U.S. Patent No. 3,385,553 to Braun in view of Fentress taken together with either McFarlane or Hoef, rejected claims 1-4 and 24 as being unpatentable over U.S. Patent No. 6,887,417 to Gawreluk et al. ("Gawreluk") taken together with U.S. Patent No. 5,057,083 to Gellman and rejected claims 5-10

as being unpatentable over any of the previous rejections as applied to claim 1 and further in view of U.S. Patent No. 6,630,086 to Goral et al.

As set forth in claims 1 and 25, the present invention is directed to a *method for one-piece injection moulding* of a soft needle catheter having a hub and a tube-shaped flexible part. *Both the hub and the tube-shaped flexible part are formed through the one-piece injection moulding method.*

The method includes the steps of feeding a molten polymer into a mould having a core which is used to form an interior of the catheter. The mould and the core together define a hub cavity and a tube-shaped cavity for forming the hub and the tube-shaped flexible part, respectively.

The step of feeding includes using a core having a cone-shaped part that extends from the hub cavity into the tube-shaped cavity and a cylindrical part that extends from the distal end (distal relative to the hub) of the cone-shaped part. This core is used to create, *within the tube-shaped cavity*, a tube-shaped flexible part having a cylindrical portion and a cone-shaped portion extending between the hub cavity and the cylindrical portion. The cone-shaped portion facilitates removal of the core when the polymer has been sufficiently cured for the core to be

removed. The resulting soft needle catheter formed from the above-described *one-step* injection moulding method is then removed from the mould when the polymer has been sufficiently cured to be removed. This method of forming a soft needle catheter having a tube-shaped cavity with a cone-shaped part in combination with a cylindrical part at the distal end of the tube-shaped cavity *in a one-step injection moulding process* is not shown or suggested by the prior art.

Fentress discloses a catheter assembly having a hub portion 20, 120 and a catheter portion 50, 150. According to Fentress, it is preferable if both the hub and catheter portions are made to include at least a slight draft angle to aid in removing the catheter from the mold (see paragraph [0058] and [0063]). In paragraph [0130], Fentress states that both the external and internal surfaces may include a slight draft angle so that the catheter assembly 110 has a slightly tapered shape; alternatively, the draft angle of the catheter assembly 110 may be zero degrees. There is nothing, however, to suggest that the catheter portion of Fentress should have *both* a *cylindrical part and a conical part internally*. On the contrary, the cited paragraphs clearly imply that the slight draft angle should be provided *along the full length of the catheter portion*, Fentress

stating in paragraph [0058] (and paragraph [0063]) that "... the hub portion 20 (120) and the catheter portion 50 (150) are each slightly wider at their proximal ends than at their distal ends."

In Hoef, the catheter portion is formed of a heat shrinkable plastic, i.e., *the "cylindrical portion" of the catheter portion is not formed during the molding process*. It is also evident from the text of Hoef that a main reason for heat shrinking the end of the catheter is that "a catheter of this type should preferably be tapered at the forward end so that the diameter of that portion of the assembly entering the vein of the patient is only slightly larger than the needle" (column 1, lines 45-54).

Hence, while Hoef teaches that it is important that the outer wall of the catheter portion be close to the insertion needle and that the catheter should have a close fit around the needle, according to Hoef this close fit is achieved *after* the production of the catheter. Hoef does not teach or suggest a method by which a close fit between the catheter and the needle is produced *during a one-step process of injection molding*. Instead, Hoef teaches a two-step process where the tapering of the tip takes place after the catheter has been produced.

As discussed more fully in a previous Amendment filed on November 27, 2006, McFarlane discloses a method of in-line

injection moulding using a mould cavity portion 20 having a cylindrical cavity 24 around the core pin 22 and a widened upper area around the core pin head 23 representing the hub cavity. The cylindrical cavity 24 has a constant inner diameter in the portion extending from the hub so that McFarlane does not disclose a cone-shaped part between the cylindrical cavity 24 and the hub 23.

In addition, like Hoef, the process by which McFarlane produces a tapered tip also requires two steps, with the tapered tip being produced after the catheter has been manufactured. This is described in the text of the patent describing Figures 2-9 thereof (see, for example, column 4, lines 33-40).

With reference to Fentress, Hoef and McFarlane, the problem being solved by the present invention is not to recognize that the catheter should be tightly joined to the insertion needle during insertion but to realize a method by which this tightness is accomplished during a one-step injection molding process. This one-step injection molding process as explained above and claimed herein is not shown or suggested by the prior art.

Braun also fails to teach a one-step injection molding process that produces a catheter having the structural components claimed, rendering Braun inadequate whether taken alone or in combination with Fentress, McFarlane or Hoef to make the present

invention obvious. Were Braun to be modified by Fentress, as the Examiner suggests, the resulting catheter would be tapered, i.e., would have a slight draft, along *the entire length* of the catheter portion. There is nothing in either Fentress of Braun to suggest that the catheter portion should have both a cylindrical part and a conical part internally in the manner being claimed herein, and nothing in any of these four references to teach a one-step injection molding process to obtain this structure.

Gawreluk discloses a sleeve assembly 16 for a catheter introducer 10 which includes a hub 32 and a tube-shaped flexible part or sleeve 30. According to Gawreluk, the sleeve may have a slight draft angle or may have a draft angle of zero degrees (see column 7, lines 24-26 and lines 37-38). There is nothing in Gawreluk that teaches or suggests that the sleeve should include both a tapered inside portion and a cylindrical inside portion as claimed by the present invention.

Gellman is directed to a vascular dilator having walls thick enough to provide a guide for a catheter assembly. This device cannot be compared to a soft needle catheter such as is described in the present application. Specifically, the manufacturers of vascular dilators are not faced with the same problems as those encountered by the manufacturers of soft needle

catheters, making vascular dilator technology inapposite to this application.

For at least the foregoing reasons, claims 1 and 25 are allowable over the cited art and favorable reconsideration and allowance thereof is requested. Claims 2-10, 24 and 26-34 are also allowable as claims properly dependent on an allowable base claim and for the subject matter contained therein.

Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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